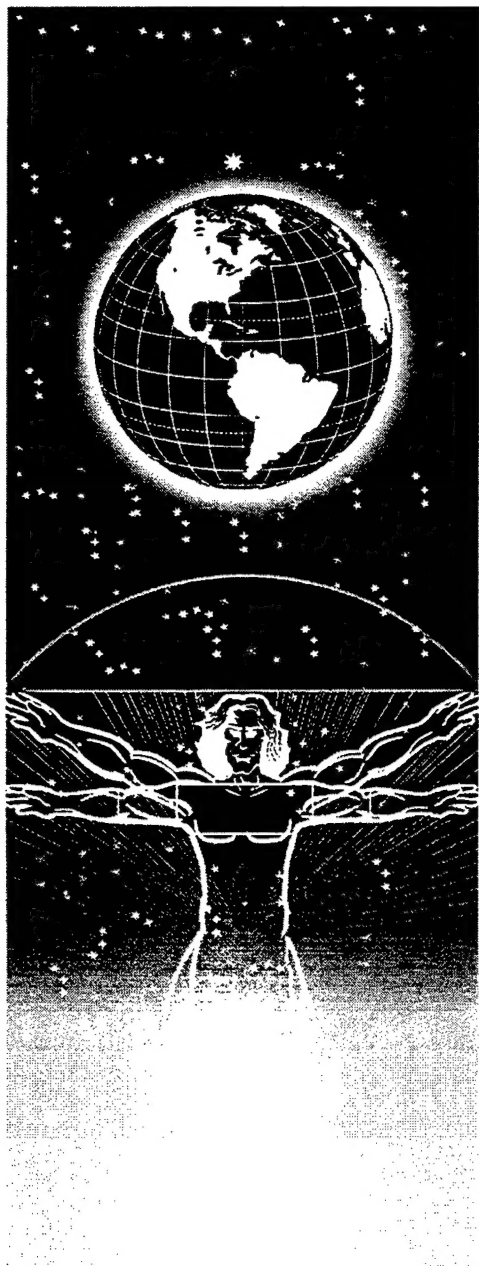


**UNITED STATES AIR FORCE
RESEARCH LABORATORY**



**TESTING AND EVALUATION OF THE
STÖCKERT SHILEY
MULTIFLOW ROLLER PUMP MODULE,
10H SERIES, MODEL 10-10-00**

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15 December 1998

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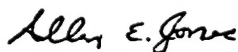
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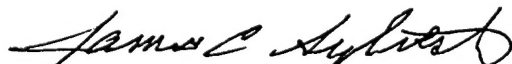
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**TESTING AND EVALUATION OF THE
STÖCKERT SHILEY
MULTIFLOW ROLLER PUMP MODULE
10H SERIES, MODEL 10-10-00**

BACKGROUND

HSD/YAM requested Aeromedical Research on behalf of the of Wilford Hall Medical Center's Extracorporeal Membrane Oxygenation (ECMO) team to evaluate the Stöckert Shiley Computer Aided Perfusion System (CAPS) for use on board USAF aeromedical evacuation aircraft. The CAPS components submitted for evaluation consisted of the Stöckert Shiley Multiflow Roller Pump Module 10H Series, Model 10-10-00; Dual Pressure Control Module; and Low Level Detector Bubble Monitor. The Dual Pressure Control Module and Low Level Detector Bubble Monitor did not pass vibration testing and were withdrawn from testing. The ECMO team director requested the Stöckert Shiley Multiflow Roller Pump Module continue through testing. Testing continued because the pump module could be utilized without the components not passing vibration testing. The Stöckert Shiley Multiflow Roller Pump Module is one of the components of the Neonatal/Pediatric ECMO Transport System. Specific components of the Stöckert Shiley Multiflow Roller Pump Module evaluated included the following: the Stöckert Shiley Multiflow Roller Pump Module and a neonatal ECMO circuit. Throughout this report, the term Equipment Under Test (EUT) refers to the Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00 and the neonatal ECMO circuit.

DESCRIPTION

The EUT is a 115 VAC/60 Hz precision peristaltic pump. It is an integral component of the Neonatal/Pediatric ECMO Transport System, Model WHMC-96. The EUT is to be positioned on the Neonatal/Pediatric ECMO Transport Gurney which includes a Venous Controller (referred to as a "bladder box") and a Topaz Uninterruptible Power Supply (UPS) which powers the EUT if AC power is interrupted. The EUT is plugged in series into the bladder box, then into the modified Tripplite Isobar, then into the Topaz UPS, then into 115 VAC/60 Hz aircraft power. The EUT is plugged into the bladder box. The bladder box is placed in the "Run" mode, its power cord plugged into the Topaz, and the Topaz plugged into aircraft 115 VAC, 60 Hz power. An example of this sequence is listed below:

Roller Pump → Bladder box → Modified Tripplite Isobar → Topaz UPS → 115 VAC/60 Hz power
The EUT accommodates a wide range of flow rates using different tubing diameters together with the different size tubing inserts available for the monitor. The EUT is capable of displaying both revolutions per minute (RPM), and flow rates in liters per minute (LPM). Only LPM's should be displayed during an aeromedical evacuation ECMO transport.

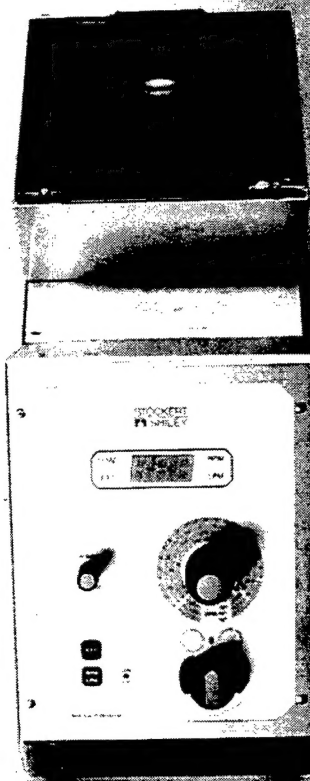


Figure 1. Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), various military standards (3-5 & 6-8), and manufacturer's literature (9). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check was developed specific to this EUT. It was used to verify EUT proper functioning under various testing conditions. Unless otherwise noted, all testing is conducted and monitored by AFMEDL personnel assigned to the Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas.

The EUT was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration
3. Electromagnetic Interference (EMI)
4. Thermal/Humidity Environmental Conditions, encompassing:

- a. Hot Operation
- b. Cold Operation
- c. Humidity Operation

5. Hypobaric Conditions

- a. Cabin Pressure/Altitude
- b. Rapid Decompression to Ambient Pressure

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

- a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.
- b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (2); AFI 41-201, Equipment Management in Hospitals (3). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.
- c. The EUT was examined to ensure it met basic requirements for human factor design as outlined in MIL-STD 1472 (4).
- d. A test setup and performance check was developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The EUT and neonatal ECMO circuit were assembled according to manufacturer's instructions for use (9) and the WHMC ECMO Specialist Training Manual (11). The EUT was placed on a level surface and operated from 115V AC power. Tubing inserts were installed into the EUT tubing clamps. The 1/4" tubing, 3/8" raceway Neonatal ECMO circuit was placed into EUT head raceway. A straight connector was used to connect the venous and arterial portions of the ECMO circuit. The tubing was locked in place by closing and locking the tubing clamps. The rotor pump head was assessed by hand rotation to assure it turned smoothly prior to electrical power activation. The power switch was positioned to the "On" position, and the direction switch rotated to the clockwise position. The EUT was calibrated according to the manufacturer's instructions for use (9). The flow rate was set to 6.0 LPM.

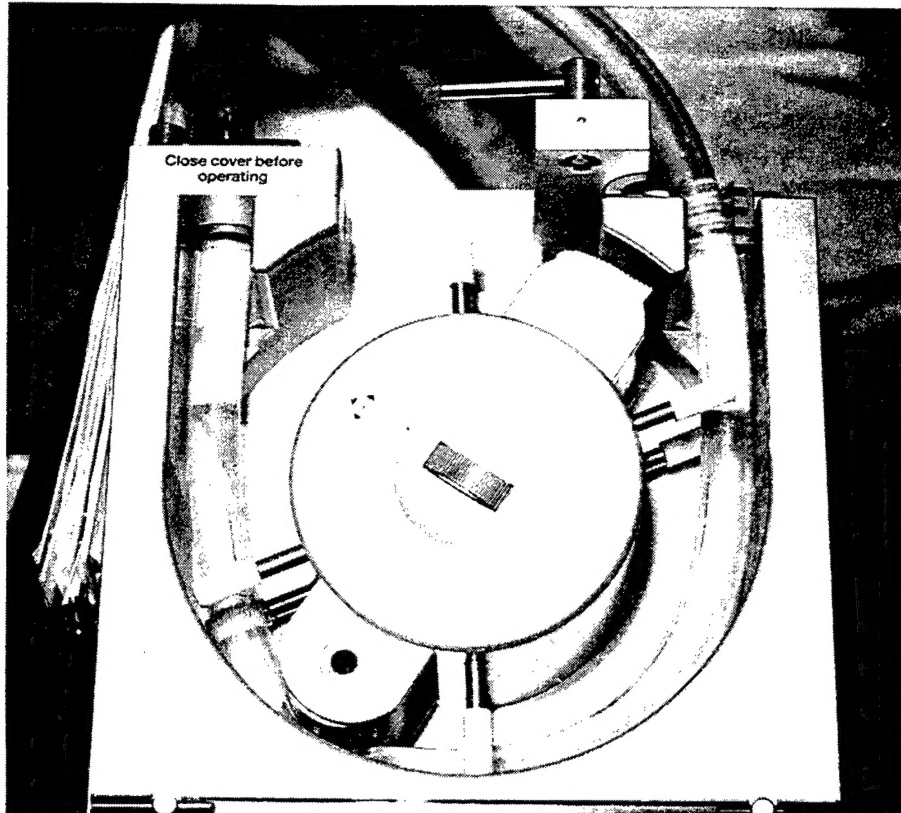


Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions. The numeric liter per minute (LPM) value displayed was evaluated and documented. It was considered acceptable if it was within 10 % of baseline LPM value. The LPM flowrate was confirmed by delivering the fluid output into a graduated cylinder. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6). Testing was conducted using a calibrated Unholtz-Dickie Vibration System, controller model UD-VWIN and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT was secured directly to the vibration system adapter/mounting plate. It was subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

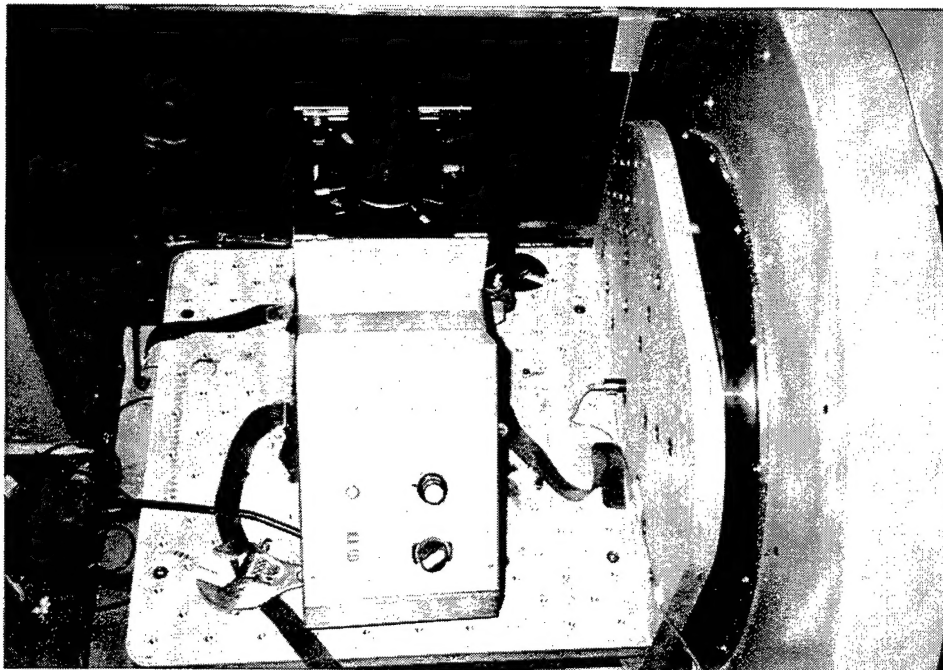


Figure 3. Vibration Table Mounting

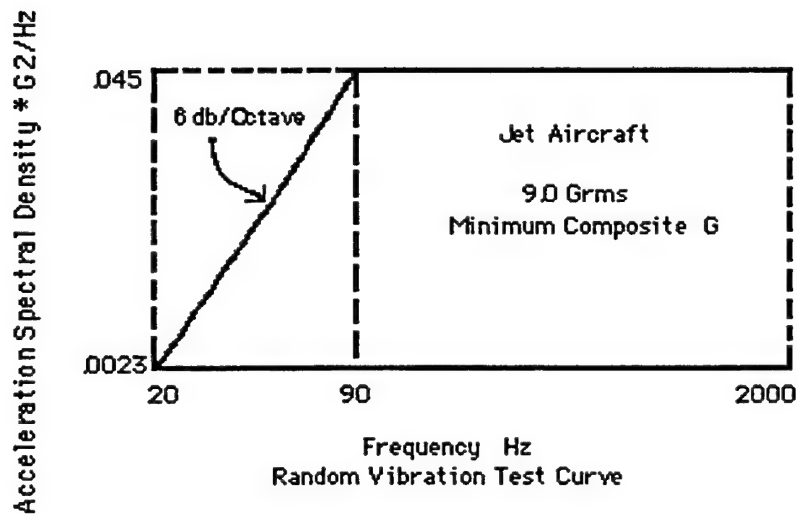
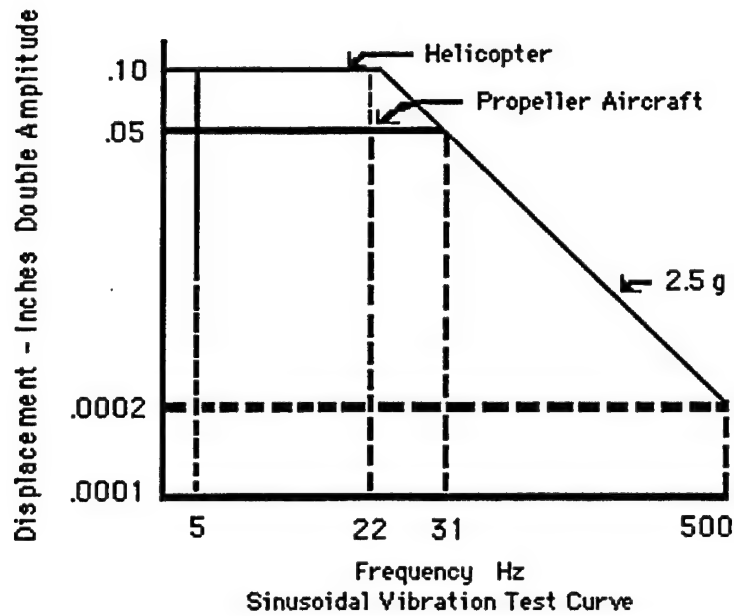


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety is the driving factor to assessing the effects of excessive electromagnetic emissions. EMI is a source of potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D & MIL-STD-462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the equipment during operation. It verifies the device's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the medical device along its power supply lines. It was performed to assess the device's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category Aircraft Internal). This test evaluated the device's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT's ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (6). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Air Force Research Laboratory's A-7 Environmental Chamber. The EUT was placed in the center of the calibrated environmental chamber. During environmental testing the EUT was monitored continuously, and a performance check was conducted every 15 minutes. The following describes the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 4 hours
- b. Hot Temp Operation: $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($49^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hours
- c. Cold Temp Operation: $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$ ($0^{\circ}\text{C} \pm 4^{\circ}\text{C}$) for 2 hours

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 10,000 ft; stopping at 2,000 ft increments for performance checks; and then descending back to ground, at rates of 5,000 ft/min. Descent is stopped at 2,000 ft for performance checks.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD so as not endanger a patient, personnel, or the aircraft itself. The EUT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 40,000 ft over a period of 60 seconds, held at 40,000 ft for a few minutes, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice more; once for a 7-second RD and once for a 1-second RD. The EUT was monitored throughout the series of decompressions; performance checks were assessed each time the unit returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their proposed operational environment, Aeromedical Research verifies demonstration of all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by qualified aeromedical crew members from Aeromedical Research on C-9 and C-141 aeromedical evacuation missions. The EUT was positioned and secured to the neonatal/pediatric ECMO transport cart and evaluated. Human factors characteristics, securing methods, setup/tear down times and securing locations were also evaluated. Feedback from ECMO team members, and other aeromedical evacuation crew members participating in delivery of patient care was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

3. Stöckert Shiley Multiflow Roller Pump Module, 10H Series, Model 10-10-00

The maximum flowrate authorized is 5.82 LPM since the pump had electromagnetic interference (EMI) when the flowrate was set above 5.82 LPM. Its operation was within expected parameters when subjected to vibration, cold and humid environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The pump is conditionally acceptable for use, therefore, the following requirements apply:

a. Plugged in as follows:

- 1) Plugged in series into the Venous Controller/Blood Pump Regulator ("bladder box"), then into the modified Tripplite Isobar, then into the Topaz UPS, then into 115 VAC/60 Hz aircraft power.

Example: Roller Pump → Bladder box → Modified Tripplite Isobar → 115 VAC/60 Hz power

2) Must be plugged into a modified Tripplite® Isobar Model IB-4 noise filter and transient voltage surge suppresser to reduce EMI below limits

2) Must be plugged into a Topaz Uninterruptible Power Supply to provide battery support

b. Flowrate set at 5.82 LPM or less

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits.

VIBRATION

The EUT operated within expected parameters during vibration testing.

ELECTROMAGNETIC COMPATIBILITY

The EUT had conducted emissions in excess of MIL-STD-461D limits when plugged directly into 115 VAC / 60 Hz aircraft power. The EUT was then plugged into a Tripplite® Isobar Model IB-4 noise filter/transient voltage surge suppresser. It failed CE102 with the flowrate set at 6 LPM. The test was repeated, but the EUT still failed CE102 when the flowrate was reduced to 5.82 LPM. WL/AAWS conducted investigative Electromagnetic Interference (EMI) modifications to the EUT but were unable to lower the EUT's emissions. The EMI modifications were removed from the EUT, and investigative EMI modifications were done on the Tripplite® Isobar Model IB-4. With the EUT connected to the modified surge suppresser, the EUT continued to fail CE102 with the flowrate set at 6 LPM. The flow rate was decreased in an attempt to pass CE102. The flowrate that did not have conducted emissions in excess of MIL-STD-461D limits was 5.82 LPM. The ECMO director was notified that the greatest flowrate possible to pass CE102 was 5.82 LPM. The ECMO director stated that flowrate was acceptable because it could still accommodate a 60 kg patient ECMO patient. The flowrate was left at 5.82 LPM for the duration of testing, and operated within expected parameters during testing.

ASC/ENAI, Wright-Patterson AFB certified the EUT for use during all phases of flight on all U.S. Air Force aircraft while plugged into a Tripplite® Isobar Model IB-4, and operating from 115 VAC / 60 Hz power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT operated within expected parameters during hot, cold, and humidity operation testing. The Hot and Cold Temperature Storage tests were not done because the EUT will not be subjected to storage with war readiness materials (WRM). The EUT will accompany the ECMO team to and from Lackland AFB to the medical treatment facility where the patient is located.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT operated within expected parameters during hypobaric testing.
2. Rapid Decompression: The EUT operated within expected parameters following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on C-9 and C-141 aeromedical evacuation missions. The EUT was secured to the Neonatal/Pediatric ECMO Patient Transport Cart as one of the components of the Neonatal/Pediatric ECMO System. Evaluation confirmed that the unit would operate within expected parameters during all phases of flight. When switching from power cart/APU to aircraft power, the EUT continued to operate in spite of the momentary power interruption that commonly occurs.

SUMMARY

Aeromedical Research found the Neonatal/Pediatric ECMO Transport System conditionally acceptable for use on large bodied U.S. Air Force aeromedical evacuation aircraft. The maximum flowrate authorized is 5.82 LPM since the EUT had electromagnetic interference (EMI) when the flowrate was set above 5.82 LPM. Its operation was within expected parameters when subjected to vibration, cold and humid environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. Because it is a component of the Neonatal/Pediatric ECMO Transport System, it is only approved for use on large bodied aircraft such as the C-130, C-141, C-9, etc. Since the EUT conditionally acceptable for use, the following requirements apply:

- a. Set up and operated by ECMO team members
- b. Must be plugged into a modified Tripplite® Isobar Model IB-4 noise filter and transient voltage surge suppresser to reduce EMI
- c. Must be plugged into a Topaz Uninterruptible Power Supply (UPS) to provide battery support during ground transport
- d. Flowrate set at 5.82 LPM or less
- e. Positioned and secured to the neonatal/pediatric ECMO transport cart

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. AFI 41-203, Electrical Shock Hazards
3. AFI 41-201, Equipment Management in Hospitals
4. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
5. Emergency Care Research Institute (ECRI)
6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
8. MIL-STD-462 D, Measurement of EMI Characteristics.
9. Stöckert Shiley Multiflow Roller Pump Module Instructions For Use Manual.
10. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.
11. The Wilford Hall USAF Medical Center (WHMC) ECMO Specialist Training Manual

APPENDIX
STÖCKERT SHILEY
MULTIFLOW ROLLER PUMP MODULE,
10H SERIES, MODEL 10-10-00
SPECIFICATIONS

Pump

Direction of rotation	Clockwise or counterclockwise
Concentricity:	
Raceway	± 0.03 mm
Occlusion	± 0.03 mm
Pump Rollers	± 0.015 mm (TIR)
Belt slip rate	$\leq 8\%$ under maximum stress conditions
Flow Rates	Up to 9.99 LPM

Display

RPM control range	4 to 250 RPM
RPM display range	0 to 250 RPM
RPM readout accuracy	$\frac{\text{indicated RPM}}{\text{actual RPM}} = 1.0 \pm 0.04$
LPM display range	0 to 9.99 LPM
Slave pump accuracy	$\frac{\text{RPM Master}}{\text{RPM Slave}} \leq 1.0 \pm 0.15$ at 50 RPM 1 ± 0.1 at ≥ 100 RPM

Monitoring Outputs

Actual speed	250 RPM equivalent to +11.5 volts
Preset speed	250 RPM equivalent to -2.5 volts
Flow rate	10 LPM equivalent to +5 volts

Power Supply

Power Source	100 to 250 VAC, 50 or 60 Hz
Power Consumption	320 Watts, max.
Circuit Breaker	2.4 amperes at 115/100 VAC 1.2 amperes at 240/220 VAC

Physical

Depth	46.6 cm (18.3 inches)
Width	18 cm (7.1 inches)
Height	28.7 cm (11.3 inches)
Weight	25.1 Kg (55 lbs)
Raceway Diameter	150 mm
Roller Diameter	30.5 mm